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10/594,760	09/29/2006	Motoyoshi Inooka	8156/88314	4637

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EXAMINER	
POLANSKY, GREGG	
ART UNIT	PAPER NUMBER
1611	
MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/594,760	INOOKA ET AL.	
	Examiner	Art Unit	
	Gregg Polansky	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 January 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7 and 9-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7 and 9-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/20/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

1. Applicants' response, filed 1/14/2008, to the Office Action mailed 9/13/2007 is acknowledged. Applicants canceled Claims 8, 12 and 13, amended Claims 1, 7, 10 and 11, and presented arguments in response to the Office Action.

2. Applicants' Information Disclosure Statement, filed 3/20/2008, is acknowledged and has been reviewed.

3. Claims 1-7 and 9-11 are pending and presently under consideration.

4. Applicants' arguments have been fully considered are persuasive in part. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 103

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

6. Claims 1-6 and 9-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Koichi et al. (JP 2002-234837 Abstract and Machine Translation) in view of Hori et al. (Chem. Pharm. Bull. 47(12), 1999 (cited in Applicants' 4/4/07 IDS as Naohide H. et al.)) and Healy et al. (U.S. Patent Number 6,066,374).

Koichi et al. teach externally applied, aqueous preparations of tranilast with a concentration of 0.05% to 30% (*see* Abstract and page 2, claims 1 and 5). Koichi et al. also teach that tranilast is used as an anti-allergic drug for the treatment of allergic diseases, and keloid and hypertrophic scars (*see* page 3, paragraph 4).

Koichi et al. does not teach the photodegradation of tranilast or a light-resistant packaging container.

Hori et al. teach the photodecomposition of tranilast aqueous solution and oily gel (*see* page 1714, "Photostability of TL", and figure 2A). Hori et al. teach light-resistant packaging consisting of aluminum foil, colored glass, and UV-absorbing agent impregnated films to inhibit photodegradation of drugs (*see* page 1713, 2nd paragraph). The reference also teaches the use of UV-absorbing agents added to tranilast oily gels to inhibit the photodegradation of the tranilast (*see* Abstract).

Hori et al. does not teach a packaging container with the light transmission properties recited in the instant claims.

Healy et al. teach "a transparent, light resistant container for the storage of medicinal agents" that permits transmission of no more than 10% of light having a wavelength of between 290 nm and 450 nm (which totally encompasses the instant invention light transmission ranges), while still permitting transmission of adequate visible light to allow external visual inspection of printed characters on the medicinal agents stored in the container (*see* Abstract and column 7, Example 3). Instant Claim 6 requires an average light transmittance of 30% or higher in the wavelength range of 455 nm to 780 nm. This is the wavelength range that allows the contents of the container to

be visually inspected (*see* Instant Specification, page 12, last paragraph). This property of the container recited in the instant disclosure, is taught by Healy et al., as demonstrated by the ability to read printed characters on medicinal agents stored in the Healy et al. recited container (*supra*) and by the graph showing a plot of the percentage of transmission of light as a function of wavelength through the wall of the preferred container taught by Healy et al. (*see* the Healy et al., Figure). Healy et al. also teach that the United States Pharmacopeia (USP) regulations requires that "medicinal agents which are intended for oral or topical administration must be stored in a container which permits transmission into the container of no more than 10% of ultraviolet and visible light having a wavelength of between 290 nm to 450 nm" (*see* column 1, 2nd paragraph).

It would have been obvious to one of average skill in the art (such as a Ph.D. medicinal chemist or pharmacist) to combine the above teachings, being so motivated by a need to dispense tranilast in a container that protects it from photodegradation and yet still allowing visible inspection of the contents. Further motivation would come from the USP storage container light transmission regulations taught by Healy et al.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976). In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the

claimed invention. Therefore, the invention as a whole is *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

7. Applicants argue instant Claim 1 has patentability over the above cited references. Applicants urge Koichi et al.,"[do]es not teach nor suggest the packaging container through which a pharmaceutical preparation containing tranilast and/or a salt thereof can be visually observed, and is also silent about inhibiting photodegradation of tranilast and/or a salt thereof".

The Examiner is aware that the Koichi et al. reference alone does not teach all of the claim limitations. One cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Applicants argue Hori et al. "merely discloses evaluations of the photodegradation of tranilast in an oily gel and IOIN (2-Ethylhexyl isononanoate), it does not suggest the relationship between the photodegradation of tranilast in the aqueous preparation and the wavelength". The Examiner disagrees. Applicants are again directed to page 1714, "Photostability of TL" and figure 2A of the Hori et al. reference, where data are presented demonstrating photodegradation of *inter alia* aqueous tranilast. Also, the Hori et al. reference discloses the wavelength dependency of the photodegradation of tranilast within the range of 213-497 nm (*see* page 1714, left column, "(B) Wavelength Dependency of the Photodegradation of TL").

Applicants argue the type of photodegradation differs depending upon the liquid carrier (i.e., oily gel, IOIN and aqueous). This is not relevant since the type of photodegradation is not a limitation of the instant claims.

Applicants argue the Healy et al. reference teach containers intended to accommodate solid agents and does not teach or suggest characteristics of a container for aqueous preparations. The fact that Applicants have recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). There is nothing in the teaching by Healy et al. that would have precluded one from utilizing the disclosed container for use with liquids.

Applicants argue the Healy et al. reference does not suggest the technique for suppressing the photodegradation of a medicinal agent held in a container. Applicants are directed to column 1, paragraph 1 of the Healy et al. reference where it is stated that the container "inhibits transmission through the wall structure of light of a selected wavelength that could be detrimental to medicinal agents stored in the container".

The Examiner fails to see the relavence of Applicants argument that the photodegradation of tranilast "should be different between an aqueous preparation and a solid agent". The container taught by Healy et al. have the same light transmission characteristics as the instantly claimed container. It would therefore inhibit the photodegradation of tranilast in an identical manner to the instantly claimed container.

The Applicants conclude "even a skilled artisan cannot predict from the teachings of Hori et al., and Healy et al., which wavelength range of light should be blocked in order to prevent the photodegradation of tranilast in an aqueous preparation". The Examiner disagrees. Hori et al. does disclose a wavelength dependency of the photodegradation of tranilast (*supra*). Further, one of ordinary skill would have been able to determine by no more than routine experimentation the suitability of the container taught by Healy et al. for storing tranilast and inhibiting its photodegradation.

Applicants argue that since Claims 2-6, 9 and 10 depend from Claim 1, and Claim 11 has "substantially identical subject matter to that of Claim 1", they are also unobvious over Koichi et al., in view of Hori et al. and Healy et al. However, since Applicants arguments to the unobviousness of Claim 1 have not been found to be convincing, this argument is moot.

Therefore, the rejections under 35 U.S.C. 103(a), of Claims 1-6 and 9-11 are maintained.

8. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Koichi et al. (JP2002-234837) in view of Hori et al. (Chem. Pharm. Bull. 47(12), 1999) and Healy et al. (U.S. Patent Number 6,066,374) as applied to Claims 1-6 and 8-13 above, and further in view of Michitoku et al. (JP 04295428 Abstract).

Instant Claim 7 is drawn to a pharmaceutical product according to Claim 1, wherein the pharmaceutical preparation further comprises (in addition to the tranilast recited in Claim 1) at least one member selected from the group consisting of berberine, B2 vitamins, hesperidin, oxyquinoline, and BI2 vitamins.

The teachings of Koichi et al., Hori et al., and Healy et al. have been presented above.

Michitoku et al. teach hesperidin as a useful anti-allergic and anti-inflammatory agent (*see* Abstract).

Since inflammation is a common characteristic of an allergic reaction (e.g., bug bite), it would have been obvious to one of ordinary skill in the art to combine tranilast (anti-allergen) with hesperidin (anti-allergen and anti-inflammatory) to try to improve upon the therapeutic benefits of tranilast administered by itself.

Applicants argue the rejection of Claim 7, which depends from Claim 1, as being unpatentable over Koichi et al., in view of Hori et al., Healy et al. and Michitoku et al. is improper in light of their arguments to Claim 1. This argument is also not convincing because Applicants arguments to Claim 1 are not convincing for reasons given above.

Therefore, the rejection under 35 U.S.C. 103(a), of Claim 7 is maintained.

9. A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976). In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole is *prima facie* obvious to one of

ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

10. Claims 1-7 and 9-11are rejected.

11. No claims are allowed.

12. **THIS ACTION IS MADE FINAL.** Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gregg Polansky whose telephone number is (571)272-9070. The examiner can normally be reached on Mon-Thur 9:30 A.M. - 7:00 P.M. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Gregg Polansky/
Examiner, Art Unit 1611

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/Ardin Marschel/
Supervisory Patent Examiner, Art Unit 1614